NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Diana Hynek 02/06/2003
Departmental Paperwork Clearance Officer
Office of the Chief Information Officer
14th and Constitution Ave. NW.
Room 6625
Washington, DC 20230

In accordance with the Paperwork Reduction Act, OMB has taken the following action on your request for approval of a new information collection received on 11/25/2002.

TITLE: Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank

AGENCY FORM NUMBER(S): None

ACTION : APPROVED WITHOUT CHANGE
OMB NO.: 0648-0468
EXPIRATION DATE: 02/28/2006

BURDEN:	RESPONSES	HOURS	COSTS($,000)
Previous	0	0	0
New	20	40	0
Difference	20	40	0
Program Change		40	0
Adjustment		0	0

TERMS OF CLEARANCE: None

OMB Authorizing Official Title

Donald R. Arbuckle Deputy Administrator, Office of Information and Regulatory Affairs

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request
DOC/NOAA/NMFS/PR2

2. OMB control number b. [ ] None
a. 0648 -

3. Type of information collection (*check one*)
a. [✔] New Collection
b. [ ] Revision of a currently approved collection
c. [ ] Extension of a currently approved collection
d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired
e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired
f. [ ] Existing collection in use without an OMB control number
For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [✔] Regular submission
b. [ ] Emergency - Approval requested by / /
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [✔] No

6. Requested expiration date
a. [✔] Three years from approval date b. [ ] Other Specify: /

7. Title
Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank

8. Agency form number(s) (*if applicable*)

9. Keywords
'marine mammals, research'

10. Abstract

The National Marine Fisheries Serviced proposes to make available tissue specimen samples to the scientific community for research that is consistent with the goal of the National Marine Tissue Bank (NMMTB) and the Marine Mammal Health and Stranding Response Program (MMHSRP). There is only a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to requests that fulfill the goals of the NMMTB, MMHSRP and to research that would otherwise not be accomplished because of limited availability of samples.

11. Affected public (*Mark primary with "P" and all others that apply with "x"*)
a. x Individuals or households d. ___ Farms
b. x Business or other for-profit e. ___ Federal Government
c. P Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [✔] Voluntary
b. [ ] Required to obtain or retain benefits
c. [ ] Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents 10
b. Total annual responses 20
1. Percentage of these responses collected electronically 0 %
c. Total annual hours requested 40
d. Current OMB inventory 0
e. Difference 40
f. Explanation of difference
1. Program change 40
2. Adjustment

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs 0
b. Total annual costs (O&M) 0
c. Total annualized cost requested 0
d. Current OMB inventory 0
e. Difference 0
f. Explanation of difference
1. Program change
2. Adjustment

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. ___ Application for benefits e. ___ Program planning or management
b. x Program evaluation f. P Research
c. ___ General purpose statistics g. ___ Regulatory or compliance
d. ___ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [ ] Recordkeeping b. [ ] Third party disclosure
c. [✔] Reporting
1. [✔] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
7. [ ] Biennially 8. [ ] Other (describe)

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [✔] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name: Dr. Teri Rowles
Phone: 301-713-2322

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention period for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date

Agency Certification (signature of Assistant Administrator, Deputy Assistant Administrator, Line Office Chief Information Officer, head of MB staff for L.O.s, or of the Director of a Program or StaffOffice)	
Signature signed by John Oliver	Date 11/15/02
Signature of NOAA Clearance Officer	
Signature signed by Richard Roberts	Date 11/18/02

SUPPORTING STATEMENT
PROTOCOL FOR ACCESS TO TISSUE SPECIMEN SAMPLES FROM THE NATIONAL MARINE MAMMAL TISSUE BANK

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

The purpose of this collection of information is to enable NOAA to allow the scientific community the opportunity to request tissue specimen samples from the National Marine Tissue Bank (NMMTB).

The NMMTB was established in 1992 and provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other analytes of interest. The NMMTB collects, processes, and stores tissues from specific indicator species (e.g., Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales, harbor porpoise),animals from mass strandings, animals that have been obtained incidental to commercial fisheries, animals taken for subsistence purposes, biopsies, and animals from unusual mortality events.

Each tissue specimen consists of duplicate samples (denoted A and B) of approximately 150 g., each. These duplicate samples are banked in the NMMTB in separate liquid nitrogen vaporphase freezers and are maintained at -150ºC. When a portion of a tissue specimen is requested for analysis, the "B" sample of that specimen can be cryogenically homogenized and aliquoted into approximately 20 subsamples of 6 to 8 g., each. The "A" sample of each specimen remains as a bulk sample and will only be homogenized after all portions from the corresponding "B" sample have been depleted and there is sufficient justification to homogenize the remaining material. Thus, 50 percent of each specimen is available to the scientific community for research and scientific evaluations consistent with the goals of the NMMTB and 50 percent is intended for long-term storage as a more permanent archive for decades.

Under 16 U.S.C. 1421*f* section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review.

There is only a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to requests that fulfill the goals of the NMMTB, MMHSRP and to research that would otherwise not be accomplished because of limited availability of samples.

2. <u>Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with applicable NOAA Information Quality Guidelines</u>.

Requestors can apply as many times as they wish, but NMFS expects to receive only 10 applications per year.

1. Requestors must submit a written request with attached study plan to the MMHSRP Coordinator, NMFS/Office of Protected Resources.

2. The following specific information must be included in the request:

a. A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use is consistent with the goals of the NMHSRP and the NMMTB.

b. A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit.

c. Name of principal investigator, official title, and affiliated research or academic organization.

d. Specific tissue sample and quantity desired.

e. Justification for use of the banked tissue.

f. Research facility where analyses will be conducted must follow the Analytical Quality Assurance program which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. Standard reference materials for use in the analysis of marine mammal tissues can be purchased from the NIST.

g. Estimated date for completion of research, and schedule/date of subsequent reports.

h. Agreement that all requests/findings will be reported to the NMMTB and the MMHSRP Program Manager.

i. Agreement that credit and acknowledgment will be given to NMFS, US Geologic Service, NIST, U.S Fish and Wildlife Service, the NMMTB, and the collector for use of banked tissues. The applicant shall insert the following acknowledgment in all publications, abstracts or presentations:

> The specimens used in this study were provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the

collaboration of USGS, USFWS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

3. Upon submission, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:

a. Appropriate marine mammal management office for that particular species,

b. Representatives of the NMMTB Collaborating Agencies, and

c. Contributor, if applicable.

4. Shipping costs will be borne by the requester. Homogenization costs for any specimens will also be borne by the requester.

There is only a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to requests that fulfill the goals of the NMMTB, MMHSRP and to research that would otherwise not be accomplished because of limited availability of samples. The applicant shall report to the MMHSRP Program Manager all research findings based on use of the banked tissue in accordance with the schedule submitted with the application.

The Information Quality Guidelines do not apply since the information obtained will not be disseminated or used for policy or regulatory determinations.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

There will be use of electronic access associated with the request for tissue specimen samples. Requesters will be able to obtain the information to be used from the MMHSRP Web page, but will not be able to submit requests electronically.

4. Describe efforts to identify duplication.

Since NMFS expects to receive only 10 applications per year, there should not be an opportunity for duplication.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

This collection of information affects the scientific community. Part of the scientific community is composed of small businesses. However, the burden is not considered to be significant, since

only about 10 applicants will be applying for a tissue specimen sample and the estimated time to respond is 2.0 hours per request (and 2 hours for a report).

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

If the collection is not conducted, the scientific community will not have access to request marine mammal tissue specimen samples.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

The collection is consistent with OMB guidelines.

8. Provide a copy of the PRA Federal Register notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A copy of the Federal Register proposed rule is attached.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

There is no provision to provide any payment or gift to participants in this request for tissue specimen samples.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

No confidentiality is promised or provided.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

There are no sensitive questions.

12. Provide an estimate in hours of the burden of the collection of information.

NMFS estimates that approximately 10 applicants will be requesting tissue specimen samples. The estimated time required to fill out the application is 2 hours. The estimated time to report research findings is 2 hours.

10 applicants x 2.0 hours x 2 times per year = 40 hours

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection.

The annual cost to the applicant is:

Postage and copying: $3,57 per applicant.

10 x $3.57 = $35.70.

14. Provide estimates of annualized cost to the Federal government.

There will be no annualized cost to the Federal government.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

This is a program change resulting from new requirements..

16. For collections whose results will be published, outline the plans for tabulation and publication.

There are no plans to publish the results of this collection per se. The requestor will be publishing the results of their research.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.

method of achieving horizontal VOA has been determined, two major changes were made to FMVSS No. 108 relating to VOA headlamps: (1) The beam was made to be much wider and much less sensitive to horizontal misaim and, (2) no horizontal aiming screws or mechanisms other than a horizontal VHAD were permitted. Valeo needs separate aim adjustments to be incorporated for the upper beam contributors to maintain a uniform gap around the headlamp housing. As a consequence, it has petitioned to amend the standard to allow the upper beams to have their own horizontal and vertical aiming capabilities. In addition, to make the consumer aware of these additional aiming systems, Valeo recommended that the light emitting surface of each upper beam contributor be marked ''VO.''

In 1996, a Regulatory Negotiation Committee that included representatives of foreign manufacturers worked with the agency over many months to achieve a consensus on all issues and the specific text of the amendment to FMVSS No. 108 to allow VOA headlamps. Because the present aiming requirements, as applied to VOA, were part of that consensus agreement, the agency is reluctant to change these requirements, absent a compelling safety reason to do so.

During the negotiated rulemaking, all of the vehicle manufacturers represented on the committee stated that they were capable of building vehicles as accurately as needed to install VOA headlamps. However, this degree of precision in assembly adds cost.

Valeo's petition is based on two rationales. The first is a desire to have an aesthetically pleasing headlamp by overcoming inaccuracies in the design and assembly of motor vehicles such that the headlamp housing may be purposefully misaimed, within a certain range, to help assure the desired visually symmetric size of the gap between the vehicle body and the headlamp or between the headlamp reflector and the surrounding headlamp housing. The second is to achieve harmonization with European standards.

Given Valeo's, as well as other manufacturers', desire for alternative aiming systems, the agency believes it is incumbent on Valeo and the industry to develop a single, objective method for vertical and horizontal aiming all VOA headlamps which could be incorporated into FMVSS No. 108. The agency does not intend to assess individual manufacturer's petitions for alternatives to the current requirements. The agency recently used a similar rationale to deny a petition from Federal-Mogul Lighting Products (Federal-Mogul) (66 FR 42985). Federal-Mogul petitioned to amend FMVSS No. 108 to allow headlamps that are aimed visually or optically to have a horizontal adjuster system that does not have the required ±2.5 degree horizontal adjustment range or the VHAD indicator required by the standard. In addition, the agency does not expect to give up the value that simultaneous beam aim provides. The agency believes that having simply aimed headlamps generally promotes more correctly aimed headlamps in the field. This is especially important, given the low incidence of periodic headlamp aim inspection in the United States and the likely lower level of experience of the service and inspection technicians and the public.

In accordance with 49 CFR part 552, the agency has reviewed the petition and concluded that it should not be granted. Accordingly, it denies Valeo's petition.

(49 U.S.C. 30118(d) and 30120(h); delegations of authority at 49 CFR 1.50 and 501.8)

Issued on October 31, 2002.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 02–28558 Filed 11–8–02; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 021017237–2237–01; I.D. 090302F]

RIN 0648–AQ51

Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: The NMFS proposes to make available tissue specimen samples to the scientific community for research that is consistent with the goals of the National Marine Mammal Tissue Bank (NMMTB) and the Marine Mammal Health and Stranding Response Program (MMHSRP). The intent of this proposed rule is to allow the scientific community the opportunity to comment on the protocol for requests for tissue specimen samples from the NMMTB.

DATES: Comments must be received by 5 p.m. EST on December 12, 2002. Comments transmitted via e-mail will not be accepted.

ADDRESSES: Submit your comment(s) to Marine Mammal Health and Stranding Response Program (MMHSRP), Program Manager, NOAA, NMFS, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910–3282. Comments may also be sent via facsimile (fax) to 301–713–0376. To submit e-Comments (see **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: Dr. Teri Rowles, Marine Mammal Health and Stranding Response Program, 301–713–2322 ext 178.

SUPPLEMENTARY INFORMATION:

E-Comments Pilot Program

NMFS encourages the public to participate in this proposed rulemaking by submitting comments. To this end, NMFS is accepting comments by submitted mail, fax, and the Internet as part of its e-Comments pilot project (see **ADDRESSES**). The e-Comments pilot project is designed to introduce electronic rulemaking to NMFS an its constituents. The public is encouraged to use the new web site to compose and submit comments on this proposed rule and the associated supporting documents to help NMFS fully evaluate this new technology. In submitting comments, please include your name and address, indicate if you are commenting on the proposed rule or other rulemaking documents, and give the reason for each comment. If you are commenting on the proposed rule, indicate to which specific section each comment applies. NMFS also invites public comments on the e-Comments program that allows you to submit your comments on line. NMFS will consider all comments received during the comment period, regardless of how they were submitted, and NMFS may make changes in the final rule in consideration of them. Please submit your comments by only one means. Comments received from the public will become part of the public record and will be posted on the e-Comments web site http://ocio.nmfs.noaa.gov/ibrm-ssi/index.shtml after the comment period closes.

Electronic Access

Several of the background documents for the MMHSRP and the NMMTB Specimen Access Policy can be downloaded from the Health and Stranding Response Program web site at

http://www.nmfs.noaa.gov/prot__res/.PR2.

Background

The NMMTB was established in 1992 and provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other analytes of interest. The NMMTB is currently managed in collaboration with the National Institute of Standards and Technology (NIST) and is housed at the Hollins Marine Laboratory in Charleston, SC and the NIST campus in Gaithersburg, MD as part of the National Biomonitoring Specimen Bank. The NMMTB collects, processes, and stores tissues from specific indicator species (e.g., Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales, harbor porpoise), animals from mass strandings, animals that have been obtained incidental to commercial fisheries, animals taken for subsistence purposes, biopsies, and animals from unusual mortality events.

Each tissue specimen consists of duplicate samples (denoted A and B) of approximately 150 g. each. These duplicate samples are banked in the NMMTB in separate liquid nitrogen vaporphase freezers and are maintained at -150oC. When a portion of a tissue specimen is requested for analysis, the ''B'' sample of that specimen can be cryogenically homogenized and aliquoted into approximately 20 subsamples of 6 to 8 g. each. The ''A'' sample of each specimen remains as a bulk sample and will only be homogenized after all portions from the corresponding ''B'' sample have been depleted and there is sufficient justification to homogenize the remaining material. Thus, 50 percent of each specimen is available to the scientific community for research and scientific evaluations consistent with the goals of the NMMTB and 50 percent is intended for long-term storage as a more permanent archive for decades. The goal of the NMMTB is to maintain quality controlled marine mammal tissues that will permit retrospective analyses to determine environmental trends of contaminants and other analytes of interest and that will provide the highest quality samples for analyses using new and innovative techniques.

Under 16 U.S.C. 1421*f*, section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those criteria available for public review and comment. In addition, NMFS must establish criteria for access to tissue analyses conducted pursuant to 16 U.S.C. 1421f, section 407(b) and data in the central marine mammal data base maintained under 16 U.S.C. 1421*f*, section 407(c). NMFS will establish these additional criteria in subsequent rulemaking.

There is only a very limited amount of samples available and the applicants for tissue specimen samples from the NMMTB will need to demonstrate that their research will fulfill the goals of the NMMTB and MMHSRP and that comparable tissue samples to accomplish the goals of the proposed research could not be readily obtained from other sources. The goal of the MMHSRP is to facilitate the collection and dissemination of reference data on marine mammals and health trends of marine mammal populations in the wild; to correlate the health of marine mammals and marine mammal populations in the wild with available data on physical, chemical, and biological environmental parameters; and to coordinate effective responses to unusual mortality events.

How To Apply

1. Applicants must submit a written request with attached study plan to the MMHSRP Program Manager, NMFS/Office of Protected Resources (see **ADDRESSES**).

2. The following specific information must be included in the request:

a. A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use is consistent with the goals of the NMMTB and the MMHSRP.

b. A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit,

c. Name of principal investigator, official title, and affiliated research or academic organization;

d. Specific tissue sample and quantity desired;

e. Justification for use of banked tissue;

f. Research facility where analyses will be conducted. The applicant must demonstrate that the research facility will follow the Analytical Quality Assurance program, which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. Standard Reference Materials for use in the analysis of marine mammal tissues can be purchased from the NIST;

g. Estimated date for completion of research, and schedule/date of subsequent reports;

h. Agreement that all research/findings based on use of the banked tissue will be reported to the NMMTB and the MMHSRP Program Manager; and

i. Agreement that credit and acknowledgment will be given to NMFS, U.S. Geologic Service (USGS), NIST, U.S. Fish and Wildlife Service (USFWS), the NMMTB, and the collector for use of banked tissues. The applicant shall insert the following acknowledgment in all publications, abstracts or presentations based on research using the banked tissue:

The specimens used in this study were provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of USGS, USFWS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

3. Upon submission of a complete application, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:

a. Appropriate Federal agency (NMFS or USFWS) marine mammal management office for that particular species, and

b. Representatives of the NMMTB Collaborating Agencies (NMFS, USFWS, USGS Biological Resources Division, and NIST).

If no member of the review committee is an expert in the field that is related to the proposed research activity, any member may request an outside review of the proposal, which maybe outside of NMFS or USFWS but within the federal government.

4. Review committees for requests involving species managed by Department of the Interior will be chaired by the USFWS Representative of the NMMTB Collaborating Agencies. All other review committees will be chaired by the MMHSRP Program Manager.

5. Recommendations on the request and an evaluation of the study plan will be provided by each committee chair to the Director, Office of Protected Resources, NMFS.

6. The Director, Office of Protected Resources, NMFS, will make the final decision on release of the samples based on the advice provided by the review committee and determination that the proposed use of the banked tissue

specimen sample is consistent with the goals of the MMHSRP and the NMMTB. The Director will send a written decision to the applicant and send copies to all review committee members. If the samples are released, the response will indicate whether the samples have been homogenized and, if not, the homogenization schedule.

7. Shipping and homogenization costs related to the use of any specimens from the NMMTB will be borne by the applicant.

8. The applicant can keep or dispose of the tissue specimen sample after the research is completed.

Classification

This proposed rule contains collection-of-information requirements and, therefore, is subject to the provisions of the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Applicants will be submitting a written request with attached study plan to the MMHSRP to apply for a tissue specimen sample from the NMMTB. Applicants will also report all research/findings based on use of the banked tissue to the NMMTB and the MMHSRP Program Manager.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the usti technology. Send comments on these or any other aspects of the collection of information to the Office Of Protected Resources at the ADDRESSES above, and to OMB at the Office of Information and Regulatory Affairs, Office of Management land Budget, Washington, DC. 20503 (Attention: NOAA Desk Officer).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

This action will not have an adverse effect on marine mammals under the Marine Mammal Protection Act.

This proposed rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

This proposed rule has been determined not to be significant for the purposes of Executive Order 12866.

The Chief Counsel for Regulation at the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The facts and purpose of this rule appears in the background section of the preamble and are not repeated here. There are approximately 10,000 that will be eligible to apply for tissue samples under this rule. These entities include both large and small entities such as universities, non-profits, small businesses, and individuals. However, we anticipate that only approximately 10 applicants total will actually request tissues specimen samples. There is no fee for the sample, but there is a cost to the applicant of approximately $3.57 (Postage, $.37 plus copying (20 pages x .16) = $3.57). The copying costs would be the applicant's study plan which they will be submitting. The total for the ten anticipated applicants is $35.70 ($3.57 x 10 applicants = $35.70). Because the costs to applicants are minimal, it is concluded that this rule would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Confidential business information, Fisheries and Marine mammals, Reporting and record keeping requirements.

Dated: November 4, 2002.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory programs, national Marine Fisheries Service.

For the reasons set out in the preamble, the National Marine Fisheries Service (NMFS) proposes to amend 50 CFR part 216 as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

2. Section 216.47 is added to read as follows:

§ 216.47 Access to marine mammal tissue, analyses, and data.

(a) *Applications for the National Marine Mammal Tissue Bank samples (NMMTB).* (1) A principal investigator or holder of a scientific research permit issued in accordance with the provisions of this subpart may apply for access to a tissue specimen sample in the NMMTB. Applicants for tissue specimen samples from the NMMTB must submit a signed written request with attached study plan to the Marine Mammal Health and Stranding Response Program (MMHSRP) Program Manager, NMFS/Office of Protected Resources. The written request must include:

(i) A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use is consistent with the goals of the NMMTB and the NMHSRP.

(A) The goals of the NMHSRP are to facilitate the collection and dissemination of reference data on marine mammals and health trends of marine mammal populations in the wild; to correlate the health of marine mammals and marine mammal populations in the wild with available data on physical, chemical, and biological environmental parameters; and to coordinate effective responses to unusual mortality events.

(B) The goal of the NMMTB is to maintain quality controlled marine mammal tissues that will permit retrospective analyses to determine environmental trends of contaminants and other analytes of interest and that will provide the highest quality samples for analyses using new and innovative techniques.

(ii) A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit;

(iii) Name of principal investigator, official title, and affiliated research or academic organization;

(iv) Specific tissue sample and quantity desired;

(v) Justification for use of banked tissue;

(vi) Research facility where analyses will be conducted. The applicant must demonstrate that the research facility will follow the Analytical Quality Assurance program, which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues;

(vii) Estimated date for completion of research, and schedule/date of subsequent reports;

(viii) Agreement that all research findings based on use of the banked tissue will be reported to the NMMTB and the MMHSRP Program Manager; and

(ix) Agreement that credit and acknowledgment will be given to NMFS, US Geologic Service (USGS), National Institute of Standards and Technology (NIST), U.S. Fish and Wildlife Service (USFWS), the NMMTB, and the collector for use of banked tissues.

(2) The applicant shall report to the MMHSRP Program Manager all research findings based on use of the banked tissue in accordance with the schedule submitted with the application.

(3) The applicant shall insert the following acknowledgment in all publications, abstracts, or presentations based on research using the banked tissue:

The specimens used in this study were provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of USGS, USFWS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

(4) Upon submission of a complete application, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:

(i) Appropriate Federal agency (NMFS or USFWS) marine mammal management office for that particular species; and

(ii) Representatives of the NMMTB Collaborating Agencies (NMFS, USFS, USGS Biological Resources Division, and NIST). If no member of the review committee is an expert in the field that is related to the proposed research activity, any member may request an outside review of the proposal, which maybe outside of NMFS or USFWS but within the Federal Government.

(5) The Director, Office of Protected Resources, NMFS, will make the final decision on release of the samples based on the advice provided by the review committee and determination that the proposed use of the banked tissue specimen is consistent with the goals of the MMHSRP and the NMMTB. The Director will send a written decision to the applicant and send copies to all review committee members.

(6) The applicant will bear all shipping and homogenization costs related to use of any specimens from the NMMTB.

(7) The applicant can keep or dispose of the tissue specimen sample consistent with the provisions of the applicant's scientific research permit after the research is completed.

(b) [Reserved]

[FR Doc. 02–28512 Filed 11–8–02; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 697

[I.D. 110402A]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; Application for Exempted Fishing Permits (EFPs)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a request for EFPs to harvest American lobster; request for comments.

SUMMARY: The Administrator, Northeast Region, NMFS (Regional Administrator) has made a preliminary determination that the subject EFP application contains all the required information and warrants further consideration. The Regional Administrator has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of Federal management of the American lobster resource. However, further review and consultation may be necessary before a final determination is made to issue the EFP. Therefore, NMFS announces that the Regional Administrator proposes to issue EFPs that would allow a maximum of six vessels to conduct fishing operations that are otherwise restricted by the regulations governing the American lobster fisheries of the Northeastern United States.

The EFP involves the catching, retaining and dissecting of 200 sub-legal lobsters as part of an ongoing research project to both monitor the offshore lobster fishery and to determine the size at which offshore lobster reach reproductive maturity. The experiment would involve only one experimental trap per vessel, and a total of six vessels, for a 1–month time period in the fall of 2002 and a 1–month time period in the spring of 2003. It would not involve the authorization of any additional trap gear in the area. The six participating commercial fishing vessels will collect detailed abundance and size frequency data on the composition of lobsters in three general offshore study areas in a collaborative effort with the University of New Hampshire (UNH) and the Atlantic Offshore Lobstermen's Association (AOLA) project on an American lobster monitoring and data collection program. Part of this research includes a size at maturity study using lobsters from each of the three study areas. One of the most reliable methods to determine size at maturity involves dissection of the female ovaries and examination of the eggs. This EFP requests that each of the six participating commercial fishing vessels utilize one modified juvenile lobster collector trap each to collect a project total of 200 sub-legal lobsters that would be collected and dissected from the three study areas to accurately determine size at maturity. Therefore, this document invites comments on the issuance of EFPs to allow six commercial fishing vessels utilize a maximum of six modified lobster traps and to collect, and retain a project total of 200 sub-legal American lobsters.

DATES: Comments on this action and application for an EFP for offshore lobster monitoring and data collection must be received on or before November 27, 2002.

ADDRESSES: Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NOAA Fisheries, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Lobster EFP Proposal''. Comments may also be sent via facsimile (fax) to (978) 281–9117.

FOR FURTHER INFORMATION CONTACT: Bob Ross, Fishery Management Specialist, (978) 281–9234.

SUPPLEMENTARY INFORMATION:

Background

The regulations that govern exempted fishing, at 50 CFR 600.745(b) and 697.22 allow the Regional Administrator to authorize for limited testing, public display, data collection, exploration, health and safety, environmental clean-up, and/or hazardous removal purposes, and the targeting or incidental harvest of managed species that would otherwise be prohibited. An EFP to authorize such activity may be issued, provided there is adequate opportunity for the public to comment on the EFP application, the conservation goals and objectives of Federal management of the American lobster resource are not compromised,

-CITE-

16 USC Sec. 1421f 01/02/01

-EXPCITE-

TITLE 16 - CONSERVATION

CHAPTER 31 - MARINE MAMMAL PROTECTION

SUBCHAPTER V - MARINE MAMMAL HEALTH AND STRANDING RESPONSE

-HEAD-

Sec. 1421f. National Marine Mammal Tissue Bank and tissue analysis

-STATUTE-

(*a*) Tissue Bank

(1) In general

The Secretary shall make provision for the storage, preparation, examination, and archiving of marine mammal tissues. Tissues archived pursuant to this subsection shall be known as the ''National Marine Mammal Tissue Bank''.

(2) Guidance for marine mammal tissue collection, preparation, and archiving

The Secretary shall, in consultation with individuals with knowledge and expertise in marine science, marine mammal science, marine mammal veterinary and husbandry practices, and marine

conservation, issue guidance, after an opportunity for public review and comment, for marine mammal tissue collection, preparation, archiving, and quality control procedures, regarding -

(*A*) appropriate and uniform methods and standards for those activities to provide confidence in marine mammal tissue samples used for research; and

(B) documentation of procedures used for collecting, preparing, and archiving those samples.

(3) Source of tissue

In addition to tissues taken during marine mammal unusual mortality events, the Tissue Bank shall incorporate tissue samples taken from other sources in the wild, including -

(*A*) samples from marine mammals taken incidental to commercial fishing operations;

(B) samples from marine mammals taken for subsistence purposes;

(C) biopsy samples; and

(D) any other samples properly collected.

(b) Tissue analysis

The Secretary shall, in consultation with the Marine Mammal Commission, the Secretary of the Interior, and individuals with knowledge and experience in marine science, marine mammal science, marine mammal veterinary and husbandry practices, and marine

conservation, issue guidance, after an opportunity for public review and comment, for analyzing tissue samples (by use of the most effective and advanced diagnostic technologies and tools practicable) as *a* means to monitor and measure overall health trends in representative species or populations of marine mammals, including -

(1) the levels of, and if possible, the effects of, potentially harmful contaminants; and

(2) the frequency of, and if possible, the causes and effects of abnormal lesions or anomalies.

(c) Data base

(1) In general

The Secretary shall maintain *a* central data base which provides an effective means for tracking and accessing data on marine mammals, including relevant data on marine mammal tissues collected for and maintained in the Tissue Bank.

(2) Contents

The data base established under this subsection shall include -

(*A*) reference data on the health of marine mammals and populations of marine mammals; and

(B) data on species of marine mammals that are subject to unusual mortality events.

(d) Access

The Secretary shall, in consultation with the Secretary of the Interior, establish criteria, after an opportunity for public

review and comment, for access to -

(1) marine mammal tissues in the Tissue Bank;

(2) analyses conducted pursuant to subsection (b) of this section; and

(3) marine mammal data in the data base maintained under subsection (c) of this section;

which provide for appropriate uses of the tissues, analyses, and data by qualified scientists, including stranding network participants.

-SOURCE-

(Pub. L. 92-522, title IV, Sec. 407, formerly title III, Sec. 307, as added Pub. L. 102-587, title III, Sec. 3003(*a*), Nov. 4, 1992, 106 Stat. 5065; renumbered title IV, Sec. 407, Pub. L. 103-238, Sec. 24(b), Apr. 30, 1994, 108 Stat. 565.)

-SECREF-

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1421g, 1421h of this title.